AUG 2 9 2001

510(k) Summary

K011949

1. Company Identification

Elk Corporation
2-17-4 Yushima
Bunkyo, Tokyo, Japan
Tel. (03) 3818-1324
Fax (03) 3818-1814
e-mail elkint@ca.mbn.or.jb

2. Official Correspondent

Gary J. Allsebrook, Consultant
Regulatory Management Services
16303 Panoramic Way
San Leandro CA 94578-1116
Tel: 510-276-2648
Fax: 510-276-3559
Email: regman1@home.com

3. Date of Submission

June 19, 2001

4. Device Name

Classification Name:	*Medical Image Hard Copy Devices* were evaluated by the Radiology panel and are classified in Class II per 21 CFR §892.2040. ProCode LMC
Common/Usual Name:	Laser Imager & Video Capture
Proprietary Name:	Elk Laser Imager, Model EL-DRY 4000

5. Substantial Equivalence

Kodak DryView 8100, 510(k) number unknown

6. Device Description and Intended Use

The EL-DRY 4000 is a desk top radiographic Laser Imager. The EL-DRY 4000 digitizes image data output from medical imaging apparatus in the form of video or digital signals, then records this printing data onto the Kodak DryView laser film by mean of semiconductor laser. Digitized image data is processed to match the film size 14"x17"(35x43cm), 14"x14"(35x35cm), and formats (1,2,4,6,9,12,15,16, 20, 24), and these processed data converted into laser out put. Three different image-processing

methods are available; selection is made via the imaging pad. This system is controlled by a micro-processor, and all parameters can be set using the imaging pad. Furthermore, necessary information such as format, system status, and error indicators are all shown on an LCD readout. In addition, 15 types of LUT (characteristic of film density levels) settings are available; selection is also made using the imaging pad. The intended use of the EL-DRY 4000 is to produce radiological quality film copies of digital or video medical images.

7. Software

Elk Corporation certifies that the EL-DRY 4000 software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes, and their effects;
- Development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

Standards Applied for:

USA	UL 2601 -1
Canada	CSA-C22.2 #601-1
E.U.	IEC 60101+A1+A2
	IEC 60825
	IEC 60601-2
	MDD ANNEX I

10. Substantial Equivalence

The following product provides functions, which are substantially equivalent to this product.

Specifications	Elk, EL-DRY 4000	Kodak, DryView 8100
Exposure Method	Infra-Red Laser Diode	Infra-Red Laser Diode
Film Type	Kodak DryView Film	Kodak DryView Film
Film Size	14"x17",14"x14"	14"x17"
Pixel Size	80x80 micron	80x80 micron
Max. Number of Pixel	4,444x5398 <14"x17">	4,361x5217 <14"x17">
Formats	1,2,4,6,9,12,15,16,20,24	1,2,4,69,12,15,16,20
Interface	Video, Digital, DICOM <w/interface>	Video, Digital, DICOM <w/interface>
Number of Inputs	Up to two	1<Up to 3 with combination of 9410>
Output Grayscale	4,096 steps <12 bits>	4,096 steps <12 bits>
Image Memory	64 MB <standard> SIMM	2GB Hard Desk
Contrast Table	15 Tables	15 Tables
Interpolation	Replication, Bilinear, High-resolution Cubic Spline	Sharp, Smooth
Calibration	Automatic Calibration by mean of Imaging Pad	Automatic Image Quality Control
Magazine	125 sheets <Darkroom loading>	125 sheets <Day-light loading>
Through put	60 sheets / hour	55 sheets / hour
Power Source	100-120/200-240VAC, 50/60Hz 10/5A	100VAC, 50/60 Hz, 12A
Dimensions <WxDxH>	522x650x390mm	635x660x1168mm
Weight	70kg	188kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2001

Elk Corporation
% Mr. Gary J. Allsebrook
Regulatory Affairs Consultant
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K011949
Elk Laser Imager, Model EL-DRY 4000
Medical Image Hard Copy Device
Dated: June 19, 2001
Received: June 21, 2001
Regulatory Class: II
21 CFR 892.2040/Procode: 90 LMC

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011949

Device Name: Elk Corporation, Laser Imager, Model EL-DRY 4000

Indications For Use:

The EL-DRY 4000 digitizes image data output from medical imaging apparatus in the form of video or digital signals, then records this printing data onto the Kodak DryView laser film by mean of semiconductor laser. The intended use of the EL-DRY 4000 is to produce radiological quality film copies of digital or video medical images.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011949